



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: April 27, 2018

Subject: Efficacy Review for SU 393, EPA File Symbol 875-ROL
(DP Barcode: 444862, E-Submission: 24902)

From: Thao Pham
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P) *Thao Pham*

Thru: Kristen Willis, Team Leader
Product Science Branch
Antimicrobials Division (7510P) *Kristen Willis*

To: Zeno Bain, Team 33 / Aline Heffernan
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Diversey, Inc.
P.O. Box 19747
Charlotte, NC 28219-0747

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
2-propanol	24.7500%
Lactic Acid	4.9984%
Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides	0.0025%
Alkyl (68% C12, 32% C14) dimethyl ethyl benzyl ammonium chlorides	0.0025%
<u>Other Ingredients</u>	70.2466%
Total	100.0%

I BACKGROUND

Product Description (as packaged, as applied): Ready-to-use liquid

Submission type: New registration

Currently registered efficacy claim(s): none

Requested action(s): Register sanitization claims against bacteria.

Documents considered in this review:

- Letter from applicant to EPA dated December 6, 2017
- Data Matrix (EPA Form 8570-35)
- 16 efficacy studies (MRID 50416312-50416327)
- Proposed label dated 2/16/18
- Confidential Statement of Formula (EPA Form 8670-4) dated 11/21/17.

II PROPOSED DIRECTIONS FOR USE

“To Sanitize Hard, Non-Porous Food Contact Surfaces and Equipment:

1. Prior to sanitization, remove gross particulate matter with a warm water flush, then wash equipment with detergent or cleaning solution and follow with a potable water rinse. SU 393 can be used as the detergent or general cleaner. Apply SU 393 to the surface. Rinse with water or wipe clean. Allow to dry.
2. Apply sanitizing solution by coarse pump trigger sprayer to the equipment or surface to be treated. Allow a contact time of at least 30 seconds.
3. Allow surfaces to drain thoroughly and air dry before resuming operation. Do not rinse.

To Sanitize Non-Food Contact Surfaces:

1. Pre-clean heavily soiled hard non-porous surfaces.
2. Apply Use Solution until thoroughly wet.
3. Let stand for one (1) minute.
4. Wipe surfaces (or let air dry).”

III STUDY SUMMARIES

1.	MRID	50416312	Study Completion Date:	08/04/17			
Study Objective		Food Contact Sanitizer – Non-Halide					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23222					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Staphylococcus aureus (ATCC 6538)					
Test Method		Accuratus Lab Services Protocol #JD01042517.GDST.2, AOAC Germicidal and Detergent Sanitizing Action of Disinfectants (<i>copy provided</i>)					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	01149D3, 01149D4, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		Not Applicable					
Test conditions		Contact time	30 sec.	Temp	25.0°C	RH	--
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A					

2.	MRID	50416313	Study Completion Date:		08/04/17		
Study Objective		Food Contact Sanitizer – Non-Halide					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23221					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Escherichia coli</i> (ATCC 11229)					
Test Method		Accuratus Lab Services Protocol #JD01042517.GDST.1, AOAC Germicidal and Detergent Sanitizing Action of Disinfectants (<i>copy provided</i>)					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	01149D3, 01149D4, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		Not Applicable					
Test conditions		Contact time	30 sec.	Temp	25.0°C	RH	--
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A					

3.	MRID	50416314	Study Completion Date:		08/04/17		
Study Objective		Food Contact Sanitizer – Non-Halide					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23243					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Pseudomonas aeruginosa</i> (ATCC 15442)					
Test Method		Accuratus Lab Services Protocol #JD01042517.GDST.8, AOAC Germicidal and Detergent Sanitizing Action of Disinfectants (<i>copy provided</i>)					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	01149D3, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		Not Applicable					
Test conditions		Contact time	30 sec.	Temp	24.5°C	RH	--
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Neutralization confirmation control failed for testing on 6/8/17, due to growth in Phosphate Buffer Dilution Water (PBDW) sterility control plates. Neutralization confirmation testing was repeated for PBDW sterility control plates on 6/20/18.					

4.	MRID	50416315	Study Completion Date:		08/04/17		
Study Objective		Food Contact Sanitizer – Non-Halide					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23244					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Escherichia coli</i> O157:H7 (ATCC 43895)					
Test Method		Accuratus Lab Services Protocol #JD01042517.GDST.4, AOAC Germicidal and Detergent Sanitizing Action of Disinfectants (<i>copy provided</i>)					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	01149D3, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		Not Applicable					
Test conditions		Contact time	30 sec.	Temp	25.0°C	RH	--
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A					

5.	MRID	50416316	Study Completion Date:		08/04/17		
Study Objective		Food Contact Sanitizer – Non-Halide					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23245					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Salmonella enterica</i> (ATCC 10708)					
Test Method		Accuratus Lab Services Protocol #JD01042517.GDST.6, AOAC Germicidal and Detergent Sanitizing Action of Disinfectants (<i>copy provided</i>)					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	01149D3, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		Not Applicable					
Test conditions		Contact time	30 sec.	Temp	24.5°C	RH	--
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A					

6.	MRID	50416317	Study Completion Date:		08/03/17		
Study Objective		Non-Food Contact Surface Sanitizer					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23272					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Klebsiella pneumoniae</i> (ATCC 4352)					
Test Method		Modified ASTM 1153-14, Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (copy provided); Protocol #JD01042517.NFS.2					
Application Method		Sprayed at a distance of 6-8 inches for 3 sprays					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	01149D3, 01149D4, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		5 glass carriers (1-inch x 1-inch) per batch contaminated with 0.01 mL culture					
Test conditions		Contact time	1 min	Temp	20.0°C	RH	32%
Neutralizer		Chambers Media					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Through email correspondence, the applicant identified the composition of "chambers media" as: "1.25 mL/L 0.25N Phosphate Buffer Stock Solution, 40 g/L soy lecithin granules, and 280 mL/L Tween 80."					

7.	MRID	50416318	Study Completion Date:		08/03/17		
Study Objective		Non-Food Contact Surface Sanitizer					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23273					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Staphylococcus aureus</i> (ATCC 6538)					
Test Method		Modified ASTM 1153-14, Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (copy provided); Protocol #JD01042517.NFS.1					
Application Method		Sprayed at a distance of 6-8 inches for 3 sprays					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	01149D3, 01149D4, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		5 glass carriers (1-inch x 1-inch) per batch contaminated with 0.02 mL culture					
Test conditions		Contact time	1 min	Temp	21.4°C	RH	29%
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A					

8.	MRID	50416319	Study Completion Date:		08/04/17		
Study Objective		Food Contact Sanitizer – Non-Halide					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23274					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Listeria monocytogenes</i> (ATCC 49594)					
Test Method		Accuratus Lab Services AOAC Germicidal and Detergent Sanitizing Action of Disinfectants (<i>copy provided</i>)					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	01149D3, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		Not Applicable					
Test conditions		Contact time	30 sec.	Temp	26.0°C	RH	--
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A					

9.	MRID	50416320	Study Completion Date:		08/04/17		
Study Objective		Food Contact Sanitizer – Non-Halide					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23275					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Cronobacter sakazakii</i> (ATCC 12868)					
Test Method		Accuratus Lab Services Protocol #JD01042517.GDST.3, AOAC Germicidal and Detergent Sanitizing Action of Disinfectants (<i>copy provided</i>)					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	01149D3, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		Not Applicable					
Test conditions		Contact time	30 sec.	Temp	25.0°C	RH	--
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A					

10.	MRID	50416321	Study Completion Date:		08/11/17		
Study Objective		Food Contact Sanitizer – Non-Halide					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23277					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Salmonella enterica</i> (ATCC 13311)					
Test Method		Accuratus Lab Services Protocol #JD01042517.GDST.7, AOAC Germicidal and Detergent Sanitizing Action of Disinfectants (<i>copy provided</i>)					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	01149D3, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		Not Applicable					
Test conditions		Contact time	30 sec.	Temp	25.0°C	RH	--
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A					

11.	MRID	50416322	Study Completion Date:		08/11/17		
Study Objective		Food Contact Sanitizer – Non-Halide					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23444					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Escherichia coli</i> O26:H11 (STEC) (ATCC BAA-2196)					
Test Method		Accuratus Lab Services Protocol #JD01052317.GDST.1, AOAC Germicidal and Detergent Sanitizing Action of Disinfectants (<i>copy provided</i>)					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	01149D3, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		Not Applicable					
Test conditions		Contact time	30 sec.	Temp	25.0°C	RH	--
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A					

12.	MRID	50416323	Study Completion Date:		08/11/17		
Study Objective		Food Contact Sanitizer – Non-Halide					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23445					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Escherichia coli</i> O45:H2 (STEC) (ATCC BAA-2193)					
Test Method		Accuratus Lab Services Protocol #JD01052317.GDST.2, AOAC Germicidal and Detergent Sanitizing Action of Disinfectants (<i>copy provided</i>)					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	01149D3, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		Not Applicable					
Test conditions		Contact time	30 sec.	Temp	25.0°C	RH	--
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A					

13.	MRID	50416324	Study Completion Date:		08/11/17		
Study Objective		Food Contact Sanitizer – Non-Halide					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23446					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Escherichia coli</i> O111:NM (STEC) (ATCC BAA-2440)					
Test Method		Accuratus Lab Services Protocol #JD01052317.GDST.3, AOAC Germicidal and Detergent Sanitizing Action of Disinfectants (<i>copy provided</i>)					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	01149D3, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		Not Applicable					
Test conditions		Contact time	30 sec.	Temp	25.0°C	RH	--
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A					

14.	MRID	50416325	Study Completion Date:		08/09/17		
Study Objective		Food Contact Sanitizer – Non-Halide					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23479					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Escherichia coli</i> O121:H19 (STEC) (ATCC BAA-2219)					
Test Method		Accuratus Lab Services Protocol #JD01052317.GDST.4, AOAC Germicidal and Detergent Sanitizing Action of Disinfectants (<i>copy provided</i>)					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	01149D3, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		Not Applicable					
Test conditions		Contact time	30 sec.	Temp	25.0°C	RH	--
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A					

15.	MRID	50416326	Study Completion Date:		08/09/17		
Study Objective		Food Contact Sanitizer – Non-Halide					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23480					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Escherichia coli</i> O145:H18 (STEC) (ATCC BAA-2192)					
Test Method		Accuratus Lab Services Protocol #JD01052317.GDST.5, AOAC Germicidal and Detergent Sanitizing Action of Disinfectants (<i>copy provided</i>)					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	01149D3, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		Not Applicable					
Test conditions		Contact time	30 sec.	Temp	25.0°C	RH	--
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		For testing performed on 6/27/17, the technician documented the amount of test culture added to the flask containing the test substance as 99.0 mL, as opposed to 1.0 mL, as specified in the protocol. Based on the inability to confirm the amount of test culture added, the study was repeated on 7/24/17, except for the neutralization confirmation controls, which were unaffected by the deviation.					

16.	MRID	50416327	Study Completion Date:	08/04/17			
Study Objective		Food Contact Sanitizer – Non-Halide					
Testing Lab, Lab Study ID		Accuratus Lab Services, A23513					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Escherichia coli</i> O103:H11 (STEC) (ATCC BAA-2215)					
Test Method		Accuratus Lab Services Protocol #JD01061217.GDST, AOAC Germicidal and Detergent Sanitizing Action of Disinfectants (<i>copy provided</i>)					
Application Method		Liquid					
Test Substance Preparation	Name/ID	SU 393 FM011030					
	Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	01149D3, 01149D5 Tested Concentration: LCL					
	Preparation	Ready-to-use					
Soil load		No organic soil load					
Carrier type, # per lot		Not Applicable					
Test conditions		Contact time	30 sec.	Temp	25.0°C	RH	--
Neutralizer		Lethen Broth + 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		N/A					

IV STUDY RESULTS

Food Contact Sanitization – Bactericidal Efficacy

MRID	Organism	Percent Reduction			Geometric Mean (Average Log ₁₀)/Carrier
		Lot 01149D3	Lot 01149D4	Lot 01149D5	
30 second contact time, ready-to-use, no soil load					
50416312	<i>Staphylococcus aureus</i> (ATCC 6538)	>99.999	>99.999	>99.999	7.56
50416313	<i>Escherichia coli</i> (ATCC 11229)	>99.999	>99.999	>99.999	7.76
50416314	<i>Pseudomonas aeruginosa</i> (ATCC 15442)	>99.999	-	>99.999	7.57
50416315	<i>Escherichia coli</i> O157:H7 (ATCC 43895)	>99.999	-	>99.999	7.53
50416316	<i>Salmonella enterica</i> (ATCC 10708)	>99.999	-	>99.999	7.83
50416319	<i>Listeria monocytogenes</i> (ATCC 49594)	>99.999	-	>99.999	7.81

MRID	Organism	Percent Reduction			Geometric Mean (Average Log ₁₀)/Carrier
		Lot 01149D3	Lot 01149D4	Lot 01149D5	
50416320	<i>Cronobacter sakazakii</i> (ATCC 12868)	>99.999	-	>99.999	7.26
50416321	<i>Salmonella enterica</i> (ATCC 13311)	>99.999	-	>99.999	7.88
50416322	<i>Escherichia coli</i> O26:H11 (STEC) (ATCC BAA-2196)	>99.999	-	>99.999	7.54
50416323	<i>Escherichia coli</i> O45:H2 (STEC) (ATCC BAA-2193)	>99.999	-	>99.999	7.67
50416324	<i>Escherichia coli</i> O111:NM (STEC) (ATCC BAA-2440)	>99.999	-	>99.999	7.49
50416325	<i>Escherichia coli</i> O121:H19 (STEC) (ATCC BAA-2219)	>99.999	-	>99.999	7.56
50416326	<i>Escherichia coli</i> O145:H18 (STEC) (ATCC BAA-2192)	>99.999	-	>99.999	7.51
50416327	<i>Escherichia coli</i> O103:H11 (STEC) (ATCC BAA-2215)	>99.999	-	>99.999	7.23

Non-Food Contact Sanitization – Bactericidal Efficacy

Non Food Contact Sanitization - Bactericidal Efficacy					
MRID	Organism	Percent Reduction			Geometric Mean (Average Log ₁₀)/Carrier
		Lot 01149D3	Lot 01149D4	Lot 01149D5	
30 second contact time, ready-to-use, no soil load					
50416317	<i>Klebsiella pneumoniae</i> (ATCC 4352)	>99.9	>99.9	>99.9	6.17
50416318	<i>Staphylococcus aureus</i> (ATCC 6538)	>99.9	>99.9	>99.9	6.18

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50416312, 50416313, 50416315, 50416316, 50416319, 50416320, 50416321, 50416322, 50416323, 50416324, 50416325, 50416326, 50416327	Sanitizer, food contact, bactericidal	Hard, non- porous surfaces	RTU, Liquid/Spray	30 seconds	none	none	<ul style="list-style-type: none"> • <i>Staphylococcus aureus</i> (ATCC 6538) • <i>Escherichia coli</i> (ATCC 11229) • <i>Escherichia coli</i> O157:H7 (ATCC 43895) • <i>Salmonella enterica</i> (ATCC 10708) • <i>Listeria monocytogenes</i> (ATCC 49594) • <i>Cronobacter sakazakii</i> (ATCC 12868) • <i>Salmonella enterica</i> (ATCC 13311) • <i>Escherichia coli</i> O26:H11 (STEC) (ATCC BAA-2196) • <i>Escherichia coli</i> O45:H2 (STEC) (ATCC BAA-2193) • <i>Escherichia coli</i> O111: NM (STEC) (ATCC BAA-2440) • <i>Escherichia coli</i> O121:H19 (STEC) (ATCC BAA-2219) 	Yes

							<ul style="list-style-type: none"> • <i>Escherichia coli</i> O145:H18 (STEC) (ATCC BAA-2192) • <i>Escherichia coli</i> O103:H11 (STEC) (ATCC BAA-2215) 	
50416314	Sanitizer, food contact, bactericidal	Hard, non-porous surfaces	RTU, Liquid/Spray	30 seconds	none	none	<ul style="list-style-type: none"> • <i>Pseudomonas aeruginosa</i> (ATCC 15442) 	No , data is invalid due to neutralization confirmation control failure. Control should be run prior to and/or simultaneous to testing, not after. Repeat testing may be conducted to support this claim due to control failure.
50416317, 50416318	Sanitizer, non-food contact, bactericidal	Hard, non-porous surfaces	RTU, Liquid/Spray	1 minute	none	none	<ul style="list-style-type: none"> • <i>Klebsiella pneumoniae</i> (ATCC 4352) • <i>Staphylococcus aureus</i> (ATCC 6538) 	Yes

VI LABEL COMMENTS

Label Date: 02/16/18

1. The proposed label claims that the ready-to-use product, SU 393, is an effective food contact sanitizer against the following bacteria on precleaned, hard, non-porous surfaces for a 30 second contact time:

- *Staphylococcus aureus* (ATCC 6538)
- *Escherichia coli* (ATCC 11229)
- *Escherichia coli* O157:H7 (ATCC 43895)
- *Salmonella enterica* (ATCC 10708)
- *Listeria monocytogenes* (ATCC 49594)
- *Cronobacter sakazakii* (ATCC 12868)
- *Salmonella enterica* (ATCC 13311)
- *Escherichia coli* O26:H11 (STEC) (ATCC BAA-2196)
- *Escherichia coli* O45:H2 (STEC) (ATCC BAA-2193)
- *Escherichia coli* O111: NM (STEC) (ATCC BAA-2440)
- *Escherichia coli* O121:H19 (STEC) (ATCC BAA-2219)
- *Escherichia coli* O145:H18 (STEC) (ATCC BAA-2192)
- *Escherichia coli* O103:H11 (STEC) (ATCC BAA-2215)

These claims are **not acceptable**. Contact time for food contact surfaces should be labeled at a minimum of 1 minute. The data supports label claims for the above organisms as a food contact sanitizer on precleaned, hard, non-porous surfaces for a 1-minute contact time.

2. The proposed label claims that the ready-to-use product, SU 393, is an effective food contact sanitizer against the following bacteria on precleaned, hard, non-porous surfaces for a 30 second contact time:

- *Pseudomonas aeruginosa* (ATCC 15442)

This claim is **not acceptable** as it is not supported by the submitted data. Testing failed simultaneous neutralization confirmation control and thus the data is invalid. Remove this organism from the label.

3. The proposed label claims that the ready-to-use product, SU 393, is an effective nonfood contact sanitizer against the following bacteria on precleaned, hard, non-porous surfaces for a 1-minute contact time:

- *Klebsiella pneumoniae* (ATCC 4352)
- *Staphylococcus aureus* (ATCC 6538)

These claims are **acceptable** as they are supported by the submitted data.

4. Make the following changes to the proposed label:
 - a. On page 2 of the label:
 - a) Remove or revise “This product meets AOAC Germicidal and Detergent Test Standards for food contact surfaces” to “This product was tested according to AOAC Germicidal and Detergent Test Standards for food contact surfaces.
 - b) Revise *Salmonella typhimurium* to *Salmonella enterica* to reflect the strain that was tested.
 - c) Remove “combination” from “Combination cleaner and sanitizer in one product” as this may imply that it is a one-step product.
 - d) Revise “...can be used to clean and sanitize in wet and dry environments” to “can be used to clean or sanitize, when used according to the respective use instructions”. Using the product on a wet surface may result in dilution of the ready-to-use product so “wet environment” should be removed.
 - b. On page 3 of the label:
 - a) Under food contact sanitization, revise 99.99999% to 99.999%.
 - b) Under non-food contact sanitization, revise 99.99% to 99.9%.
 - c. On pages 3 and 4 of the label, revise all contact times from 30 seconds to 1 minute.